



PATENT
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. Atorvastatin calcium Form V or hydrate thereof.
2. The atorvastatin calcium Form V or hydrate thereof of claim 1 having an X-ray powder diffractogram substantially as depicted in Figure 1.
3. (Amended) [The] A crystalline form of atorvastatin calcium [Form V or] and hydrates thereof [of claim 1 having] characterized by X-ray powder diffraction peaks at about 5.5 and 8.3 degrees at 2 θ and a broad peak at about 18-23 +/- 0.2 degrees 2 θ .
4. The atorvastatin calcium Form V or hydrate thereof of claim 1 having a solid state ¹³C NMR spectrum substantially as depicted in Figure 2.
5. (Amended) [The] A crystalline form of atorvastatin calcium [Form V or] and hydrates thereof [of claim 1 having] characterized by solid state ¹³C NMR signals at about 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.
6. Atorvastatin calcium Form V containing up to about 9 moles of water per mole of atorvastatin calcium.
7. (Amended) A process for preparing a crystalline form of atorvastatin calcium [Form V, or] and hydrates thereof of either of claims 3 or 5, comprising the steps of
 - a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution
 - b) contacting the atorvastatin salt solution with a calcium salt, and
 - c) isolating the crystalline form of atorvastatin calcium [Form V] or [hydrates] hydrate thereof.

8. The process of claim 7 wherein the salt of atorvastatin is a metal salt of atorvastatin.
9. The process of claim 8 wherein the metal salt of atorvastatin is a sodium salt of atorvastatin.
10. The process of claim 7 wherein the calcium salt is calcium acetate.
11. The process of claim 7 wherein the calcium salt is dissolved in a solvent and the atorvastatin salt solution is contacted with the calcium salt by adding the calcium salt solution to the atorvastatin salt solution.
12. (Amended) A process for preparing a crystalline form of atorvastatin calcium [Form V] or [hydrates] hydrate thereof of either of claims 3 or 5 comprising the steps of
 - a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,
 - b) adding water to the atorvastatin calcium salt solution, and
 - c) isolating the crystalline form of atorvastatin calcium [Form V] or [hydrates] hydrate thereof.
13. The process of claim 12 wherein the solvent is methanol.
14. The process of claim 12 wherein the solvent is ethanol.
15. The process of claim 12 wherein the solvent is tetrahydrofuran.
16. A pharmaceutical composition comprising a therapeutic amount of atorvastatin Form V or hydrates thereof of claim 1.

17. (New) Atorvastatin calcium form V and hydrates thereof characterized by x-ray powder diffraction peaks at about 5.5 and 8.3 +/- 0.2 degrees 2 θ and ^{13}C NMR signals at about 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

18. (New) A method of making atorvastatin calcium form V and hydrates thereof comprising the steps of:

- a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution
- b) contacting the atorvastatin salt solution with a calcium salt, and
- c) isolating atorvastatin calcium Form V or hydrate thereof.

19 (New) A method of making atorvastatin calcium form V comprising the steps of:

- a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,
- b) adding water to the atorvastatin calcium salt solution, and
- c) isolating the atorvastatin calcium Form V or hydrate thereof.